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May 12, 1999

Dockets Management Branch (HFA 305)
Docket No. 98-N-1265
The Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857

The following is a comment from the North Carolina Board of Pharmacy on the proposed Memorandum of Understanding on Interstate Distribution of Compounded Drug Products.

At the April 20th meeting of the Board the members expressed concerns regarding proposals to arbitrarily limit the activities of compounding pharmacies based on total number of prescriptions (5%/20% as noted in III. C.1b.) These numbers have no basis in fact or logic and need to be either justified or removed. This provision would essentially prohibit a pharmacy from conducting business with only compounded products. If the 5%/20% has fundamental merit then it should also be applied to pharmaceutical manufacturers. If it would be good for the goose it must also be good for the gander too.

One member of the Board noted that it is not possible to effectively operate with a limited list of chemicals to be used in compounding. The number of chemical compounds available is huge and to limit pharmacist activity to a miniscule number of compounds is simply not reasonable. Public policy would seem to dictate that the burden would be on the government to show that a particular chemical is harmful rather than the other way around.

Some reference in the MOU should also note that decisions may be made on a professional basis by pharmacists based on therapeutic considerations. No such phrase is found in the most recent draft.

The North Carolina Board believes that a properly framed MOU should foster safe and effective products which would improve health care at lower prices than consumers often now pay. We urge FDA to not dwell on protecting the financial health of the pharmaceutical industry at the expense of the American public.

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Second Century Of
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05/12/99 19:14 NC RTR 276 1554

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